REMARKS

This is a full and timely response to the non-final Office Action mailed by the U.S. Patent and Trademark Office on September 21, 2005. Claims 12-17 remain pending in the present application. Claims 1-11 and 18-20 are canceled. Claim 12 is amended. Applicant respectfully submits that support for the amendment can be found in the specification at least on page 2, lines 15-22. In view of the foregoing amendments and following remarks, reconsideration and allowance of the present application and claims are respectfully requested.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 12-17 stand rejected under 35 U.S.C. § 112, First Paragraph, as failing to comply with the enablement requirement. The Office Action states:

> [t]he claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not appear to disclose how to lithograph a foam structure.

Applicant respectfully submits that only claims 14 and 15 recite a "foam structure." Therefore, Applicants respectfully submit that the rejection of claims 12, 13, 16 and 17 is improper and respectfully request that the rejection be withdrawn, at least with respect to claims 12, 13, 16 and 17. Furthermore, claim 14 recites "wherein the restrictive elements are constructed using an image of a foam structure" and claim 15 recites "wherein the restrictive elements are constructed using a simulated image of a foam structure." Specifically, an image or a simulated image of a foam structure is lithographed, not a foam structure *per se.*

With regard to claims 14 and 15, Applicant respectfully submits that the process of lithography is well known in the art. Further, Applicant respectfully submits that the foam structure as defined in the specification can be random characters, "such as closely packed granules of sand, or an image or simulation of a frit or foam structure with random characters." *See specification*, page 4, lines 18-20. The specification further states

> [t]he method for providing a tortuous path lithographs the image or simulation of a structure, for example, a sponge or fine natural frits, and etches the image into the substrate 130, 150. Etching is a preferred method for forming surface features in a wide variety of geometries, and includes such processes as common photolithography. Surface features may be formed by imaging a lithographic mask onto a suitable substrate and then etching the

> substrate in areas that are unprotected by the lithographic mask. Such masks may define all of the etched features for a selected area of the substrate, for example, and the pattern may encompass multiple pairs of component sections to be created on the substrate, each of which feature complementary sets of microstructures. The method etches the image onto the substrate 130, 150 by impressing the image onto a mask that is used to etch the substrate 130, 150.

See specification page 4, lines 21-31.

Applicant respectfully submits that the terminology "foam structure" refers to an image or a simulated image of a sponge or other structure having random features (*See* specification page 4, line 20), and is not intended to imply that the substrate material is foam. Applicant respectfully submits that lithographing what the specification refers to as a "foam structure" is no different than lithographing a pattern onto any other material from which the substrate is formed. The term "foam structure" refers to the geometry of the material that is etched and does not imply that a foam material is to be etched. Nor does the term "foam structure" imply that a particular etching technique is used to etch the substrate.

Accordingly, Applicant respectfully submits that claims 12-17 are in compliance with 35 U.S.C. § 112, First Paragraph, and requests that the rejection be withdrawn.

Rejections Under 35 U.S.C. § 102

Claims 12-17 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,814,859 to Koehler *et al.* (hereafter *Koehler*).

A proper rejection of a claim under 35 U.S.C. § 102 requires that a single prior art reference disclose each element of the claim. *See, e.g., W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303, 313 (Fed. Cir. 1983). Anticipation requires that each and every element of the claimed invention be disclosed in a single prior art reference. *See, e.g., In re Paulsen,* 30 F.3d 1475, 31 USPQ2d 1671 (Fed. Cir. 1994); *In re Spada*, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990). Alternatively, anticipation requires that each and every element of the claimed invention be embodied in a single prior art device or practice. *See, e.g., Minnesota Min. & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 24 USPQ2d 1321 (Fed. Cir. 1992). The test is the same for a process. Anticipation requires identity of the claimed process and a process of the prior art. The claimed process, including each step thereof, must have been described or embodied, either expressly or inherently, in a single reference. *See, e.g., Glaverbel S.A. v. Northlake Mkt'g & Supp., Inc.*, 45 F.3d 1550, 33 USPQ2d 1496 (Fed. Cir. 1995). Those elements must either be inherent or

disclosed expressly. *See, e.g., Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 7 USPQ2d 1057 (Fed. Cir. 1988); *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 2 USPQ2d 1051 (Fed. Cir. 1987). Those elements must also be arranged as in the claim. *See, e.g., Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ2d 1913 (Fed. Cir. 1989); *Carella v. Starlight Archery & Pro Line Co.*, 804 F.2d 135, 231 USPQ 644 (Fed. Cir. 1986). For anticipation, there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. *See, e.g., Scripps Clinic & Res. Found. v. Genentech, Inc.*, 927 F.2d 1565, 18 USPQ2d 1001 (Fed. Cir. 1991).

Accordingly, the single prior art reference must properly disclose, teach or suggest each element of the claimed invention.

The Office Action states that:

> [t]he claims are considered to read on Koehler (U.S. Patent No. 6,814,859). However, if a difference exists between the claims and Koehler (U.S. Patent No. 6,814,859), it would reside in optimizing the elements of Koehler (U.S. Patent No. 6,814,859). It would have been obvious to optimize the elements of Koehler (U.S. Patent No. 6,814,859) to enhance separation.

Koehler discloses the bonding of a single strip of polypropylene frit material into a multi-column, microfluidic separation device composed of un-oriented polypropylene films, using one strip of frit material spanning multiple separation columns. *See, Koehler*, col. 7, lines 10-13. *Koehler* further states that "[a] stationary phase material 220 is retained in the separation columns 222A-222E by a frit 226 positioned between the second device layer 216 and the third device layer 215. *See, Koehler*, col. 7, lines. 40-42.

Koehler continues stating that "[a]though various materials may be used for the frit 226, a preferred material for fabricating the frit 26 [sic] is a permeable polypropylene membrane such as, for example, 1-mil (25 microns) thickness Celgard 2500 membrane (55% porosity, 0.209x0.054 micron pore size, Celgard Inc., Charlotte, N.C.)." *See, Koehler*, col. 7, lines 62-66.

Further, *Koehler* states that [i]n an especially preferred embodiment, microfluidic devices are according to the present invention are constructed using stencil layers or sheets to define channels and/or chambers." *See, Koehler*, col. 5, lines 12-16. *Koehler* continues stating "[a]s noted previously, a stencil layer is preferably substantially planar and has a channel or chamber cut through the entire thickness of the layer to permit substantial fluid movement within that layer. *See, Koehler*, col. 5, lines 16-19.

Koehler is attempting to solve the problem of retaining a frit material within stencil-formed layers of material to form a biomolecule separation medium that performs chemical separation.

From this it is abundantly clear that *Koehler* requires that a layer of frit material be secured between at least two layers of structural material that forms one or more fluidic channels. Importantly, nowhere does *Koehler* disclose, teach or suggest features being etched onto one or more substrates, the substrates being diffusion bonded together, to form a tortuous flow path that functions as a monolithically integrated filter.

In marked contrast to *Koehler*, the present invention discloses a substrate having a tortuous flow path for fluid handling comprising restrictive elements with features of random characters, an image of the features being lithographed onto one or more substrates and etched into the one or more substrates, "wherein the one or more substrates are diffusion bonded together to form flow channels," and "an integrated tortuous flow path formed within the flow channels and functioning as integrated restrictors forming a monolithically integrated filter."

Applicant respectfully submits that at least these features are neither disclosed, taught nor suggested by *Koehler*. Applicant respectfully submits that the structure of *Koehler* prevents etching a substrate material to define features, and nowhere discloses, teaches or suggests at least "wherein the one or more substrates are diffusion bonded together to form flow channels," and "an integrated tortuous flow path formed within the flow channels and functioning as integrated restrictors forming a monolithically integrated filter," as recited in independent claim 12.

Indeed, the planar frit structure disclosed in *Koehler* is designed to be held in place between at least two planar sheets of material. Applicant has carefully reviewed *Koehler* and can find no indication of features being lithographed and etched into one or more substrates to form an integrated tortuous flow path formed within the flow channels and functioning as integrated restrictors forming a monolithically integrated filter. Applicant respectfully requests that the Examiner point to the exact location in *Koehler* where these features are shown.

Accordingly, Applicant respectfully submits that claim 12 is allowable for at least the reason that it recites features that are neither disclosed, taught nor suggested by *Koehler*. Further, Applicant respectfully submits that dependent claim 13-17, which depend from allowable independent claim 12, are allowable for at least the reason that they depend from

an allowable independent claim. *In re Fine*, 837 F.2d 1071, 5 USPQ 2d 1596, 1598 (Fed. Cir. 1998).

Rejections Under 35 U.S.C. § 103

Claims 12-17 rejected over U.S. Patent No. 6,814,859 to Koehler et al.

Claims 12-17 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Patent No. 6,814,859 to Koehler *et al.* (hereafter *Koehler*). For a claim to be properly rejected under 35 U.S.C. § 103, "[t]he PTO has the burden under section 103 to establish a *prima facie* case of obviousness. It can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references." *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988) (Citations omitted). Further, "[t]he mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." *In re Fritch*, 972 F.2d 1260, 1266, 23 U.S.P.Q.2d 1780 (Fed Cir. 1992).

The Office Action states that:

> [t]he claims are considered to read on Koehler (U.S. Patent No. 6,814,859). However, if a difference exists between the claims and Koehler (U.S. Patent No. 6,814,859), it would reside in optimizing the elements of Koehler (U.S. Patent No. 6,814,859). It would have been obvious to optimize the elements of Koehler (U.S. Patent No. 6,814,859) to enhance separation.

As previously stated, *Koehler* discloses the bonding of a single strip of polypropylene frit material into a multi-column, microfluidic separation device composed of un-oriented polypropylene films, using one strip of frit material spanning multiple separation columns. *See, Koehler*, col. 7, lines 10-13. *Koehler* further states that "[a] stationary phase material 220 is retained in the separation columns 222A-222E by a frit 226 positioned between the second device layer 216 and the third device layer 215. *See, Koehler*, col. 7, lines. 40-42.

Koehler continues stating that "[a]though various materials may be used for the frit 226, a preferred material for fabricating the frit 26 [sic] is a permeable polypropylene membrane such as, for example, 1-mil (25 microns) thickness Celgard 2500 membrane (55% porosity, 0.209x0.054 micron pore size, Celgard Inc., Charlotte, N.C.)." *See, Koehler*, col. 7, lines 62-66.

Further, *Koehler* states that [i]n an especially preferred embodiment, microfluidic devices are according to the present invention are constructed using stencil layers or sheets to

define channels and/or chambers." *See, Koehler*, col. 5, lines 12-16. *Koehler* continues stating "[a]s noted previously, a stencil layer is preferably substantially planar and has a channel or chamber cut through the entire thickness of the layer to permit substantial fluid movement within that layer. *See, Koehler*, col. 5, lines 16-19.

Koehler is attempting to solve the problem of retaining a frit material within stencil-formed layers of material to form a biomolecule separation medium that performs chemical separation.

From this it is abundantly clear that *Koehler* requires that a layer of frit material be secured between at least two layers of structural material that form one or more fluidic channels. Importantly, nowhere does *Koehler* disclose, teach or suggest features being etched onto one or more substrates, the substrates being diffusion bonded together, to form a tortuous flow path that functions as a monolithically integrated filter.

In marked contrast to *Koehler*, the present invention discloses a substrate having a tortuous flow path for fluid handling comprising restrictive elements with features of random characters, an image of the features being lithographed onto one or more substrates and etched into the one or more substrates, "wherein the one or more substrates are diffusion bonded together to form flow channels," and "an integrated tortuous flow path formed within the flow channels and functioning as integrated restrictors forming a monolithically integrated filter."

Applicant respectfully submits that at least these features are neither disclosed, taught nor suggested by *Koehler*. Nor would these features be obvious to one having ordinary skill in the art after reviewing *Koehler*. Applicant respectfully submits that the structure of *Koehler* prevents etching a substrate material to define features, and nowhere discloses, teaches or suggests at least "wherein the one or more substrates are diffusion bonded together to form flow channels," and "an integrated tortuous flow path formed within the flow channels and functioning as integrated restrictors forming a monolithically integrated filter," as recited in independent claim 12. For at least this reason, Applicant respectfully submits that *Koehler* teaches away from the present invention.

Indeed, the planar frit structure disclosed in *Koehler* is designed to be held in place between at least two planar sheets of material. Applicant has carefully reviewed *Koehler* and can find no indication of features being lithographed and etched into one or more substrates to form an integrated tortuous flow path formed within the flow channels and functioning as integrated restrictors forming a monolithically integrated filter.

Accordingly, Applicant respectfully submits that claim 12 is allowable for at least the reason that it recites features that are neither disclosed, taught nor suggested by *Koehler*. Further, Applicant respectfully submits that dependent claim 13-17, which depend from allowable independent claim 12, are allowable for at least the reason that they depend from an allowable independent claim. *In re Fine,* 837 F.2d 1071, 5 USPQ 2d 1596, 1598 (Fed. Cir. 1998).

Claims 12-17 rejected over *Koehler* in view of U.S. Patent No. 3,840,343 to Reidmann et al. or U.S. Patent No. 3,988,225 to Schulze

Claims 12-17 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over *Koehler* in view of either U.S. Patent No. 3,840,343 to Reidmann *et al.* (hereafter *Reidmann*) or U.S. Patent No. 3,988,225 to Schulze (hereafter *Schulze*).

The Office Action states that:

> [a]t best, the claims differ from Koehler (U.S. Patent No. 6,814,859) in implying the frit has a foam structure. Reidmann (U.S. Patent No. 3,840,343) (column 2, lines 13-15) discloses that it is desirable to use a foam structure as a frit material. Schulze (U.S. Patent No. 3,988,225) (column 2, line 67-column 3, line 2) discloses that it is desirable to use foam as a frit material. It would have been obvious to use a foam structure as a frit material in Koehler (U.S. Patent No. 6,814,859) either because Reidmann (U.S. PatentNo. 3,840,343) (column 2, lines 13-15) discloses that it is desirable to use a foam structure as a frit material or because Schulze (U.S. Patent No. 3,988,225) (column 2, line 67-column 3, line 2) discloses that it is desirable to use foam as a frit material.

As stated above, *Koehler* discloses the bonding of a single strip of polypropylene frit material into a multi-column, microfluidic separation device composed of un-oriented polypropylene films, using one strip of frit material spanning multiple separation columns. *See, Koehler*, col. 7, lines 10-13. *Koehler* further states that "[a] stationary phase material 220 is retained in the separation columns 222A-222E by a frit 226 positioned between the second device layer 216 and the third device layer 215. *See, Koehler*, col. 7, lines. 40-42.

Reidmann discloses a flame ionization detector that includes a metal foam frit. *Schulze* discloses a process for the prevention of supersaturation of electrolytes from nonferrous metal refining with arsenic, antimony and bismuth in which the electrolyte solution is brought into contact with a chemisorption agent on a flat substrate. The substrate with the chemisorption agent is brought into a compact form with neighboring substrates and is enclosed in a protective housing before being contacted with the electrolyte. *Schulze* also

discloses the use of foam as a frit material.

However, while *Reidmann* and *Schulze* each disclose the use of foam as a frit material, neither *Reidmann* nor *Schulze* cure the defect of *Koehler* in that the proposed combination fails to disclose, teach or suggest at least a substrate having a tortuous flow path for fluid handling comprising restrictive elements with features of random characters, an image of the features being lithographed onto one or more substrates and etched into the one or more substrates, "wherein the one or more substrates are diffusion bonded together to form flow channels," and "an integrated tortuous flow path formed within the flow channels and functioning as integrated restrictors forming a monolithically integrated filter."

Applicant respectfully submits that at least these features are neither disclosed, taught nor suggested by either proposed combination. Nor would these features be obvious to one having ordinary skill in the art after reviewing either proposed combination. Applicant respectfully submits that the structure of *Koehler* prevents etching a substrate material to define features, and nowhere discloses, teaches or suggests at least "wherein the one or more substrates are diffusion bonded together to form flow channels," and "an integrated tortuous flow path formed within the flow channels and functioning as integrated restrictors forming a monolithically integrated filter," as recited in independent claim 12.

Further, the mere mention of a foam frit in *Reidmann* and *Schulze* fail to disclose, teach or suggest the elements mentioned above in claim 12. Nor would the frits disclosed in *Reidmann* or *Schulze* work in the device of *Koehler* because the device of *Koehler* is planar.

Indeed, the planar frit structure disclosed in *Koehler* is designed to be held in place between least two planar stenciled sheets of material. Applicant has carefully reviewed the proposed combination and can find no indication of features being lithographed and etched into one or more substrates to form an integrated tortuous flow path formed within the flow channels and functioning as integrated restrictors forming a monolithically integrated filter.

Accordingly, Applicant respectfully submits that claim 12 is allowable for at least the reason that it recites features that are neither disclosed, taught nor suggested by either proposed combination. Further, Applicant respectfully submits that dependent claim 13-17, which depend from allowable independent claim 12, are allowable for at least the reason that they depend from an allowable independent claim. *In re Fine,* 837 F.2d 1071, 5 USPQ 2d 1596, 1598 (Fed. Cir. 1998).

Claims 12-17 rejected over U.S. Patent No. 5,938,923 to Tu et al. or U. S. Patent No. 5,540,849 to Dugan in view of U.S. Patent No. 6,673,285 to Ma

Claims 12-17 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over either U.S. Patent No. 5,938,923 to Tu *et al.* (hereafter *Tu)* or U.S. Patent No. 5,540,849 to Dugan (hereafter *Dugan)* in view of U.S. Patent No. 6,673,285 to Ma (hereafter *Ma*).

The Office Action states that:

> [a]t best, the claims differ from either Tu (U.S. Patent No. 5,938,923) or Dugan (U.S. Patent No. 5,540,849) in implying use of a foam structure. Ma (U.S. Patent No. 6,673,285) (column 1, lines 11-15 and 19; column 14, lines 52-55 and 64-65; column 15, lines 2-3) discloses that his foam skeleton porous material is useful as filter material and has the advantage over lithography by not requiring sophisticated equipment, is easily automated for large scale production, and has a well controlled nature in architecture, inter-pore conductivity, physical and mechanical properties. It would have been obvious to use Ma (U.S. Patent No. 6,673,285)'s foam structure in either Tu (U.S. Patent No. 5,938,923) or Dugan (U.S. Patent No. 5,540,849) because Ma (U.S. Patent No. 6,673,285) (column 1, lines 11-15 and 19; column 14, lines 52-55 and 64-65; column 15, lines 2-3) discloses that his foam skeleton porous material is useful as filter material and has the advantage over lithography by not requiring sophisticated equipment, is easily automated for large scale production, and has a well controlled nature in architecture, inter-pore conductivity, physical and mechanical properties.

Tu discloses a microfabricated filter made up of two bonded substrate structures, each consisting of single crystalline silicon. The pores of the filter consist of one or more channels disposed between the two substrate structures. The width of the channels are defined by a thickness of a sacrificial layer formed on one of the substrate structures. *See, Tu* abstract. *Tu* states that "[a] dimension of the each channel is defined by depositing and removing a thickness of a sacrificial layer formed on the first substrate structure. *See, Tu,* col. 2, lines 5-7.

Dugan discloses a filter for filtering particulates from a particulate-containing fluid stream passing through the filter. The filter contains one or more flow plates, each of the flow plates having (a) one or more primary fluid flow passages; and (b) one or more particulates-collecting, eddy current-forming accumulation chambers communicating with the primary fluid flow passages; wherein the accumulation chambers are not situated in the primary fluid flow passages and, when the accumulation chambers contain articulates, the particulate-containing accumulation chambers do not impede fluid flow through the primary fluid flow passages. *See, Dugan,* Abstract.

Ma discloses three-dimensional biodegradable, porous, polymer (natural or synthetic) scaffolds with well-controlled, interconnected pores, and method for forming the porous materials. *See, Ma* abstract.

However, while *Tu* discloses a mechanical filtration structure, *Dugan* discloses a structure that isolates particulates from a fluid flow channel, and *Ma* discloses a porous polymer scaffold structure with well controlled interconnected pores, the proposed combination of either *Tu* and *Ma* or *Dugan* and *Ma* fail to disclose, teach or suggest Applicant's substrate having a tortuous flow path for fluid handling comprising restrictive elements with features of random characters, "***an image of the features being lithographed onto one or more substrates and etched into the one or more substrates***," "wherein the one or more substrates are diffusion bonded together to form flow channels," and "an integrated tortuous flow path formed within the flow channels and functioning as integrated restrictors forming a monolithically integrated filter."

Merely adding the porous polymer scaffold structure of *Ma* into the filter of *Tu* does not result in Applicant's substrate having a tortuous flow path for fluid handling comprising restrictive elements with features of random characters, "***an image of the features being lithographed onto one or more substrates and etched into the one or more substrates***," "wherein the one or more substrates are diffusion bonded together to form flow channels," and "an integrated tortuous flow path formed within the flow channels and functioning as integrated restrictors forming a monolithically integrated filter."

Nor does adding the porous polymer scaffold structure of *Ma* into the filter of *Dugan* does not result in Applicant's substrate having a tortuous flow path for fluid handling comprising restrictive elements with features of random characters, "***an image of the features being lithographed onto one or more substrates and etched into the one or more substrates***," "wherein the one or more substrates are diffusion bonded together to form flow channels," and "an integrated tortuous flow path formed within the flow channels and functioning as integrated restrictors forming a monolithically integrated filter."

Applicant respectfully submits that at least these features are neither disclosed, taught nor suggested by either of the proposed combinations. Nor are these features obvious after reviewing each of the proposed combinations.

Accordingly, Applicant respectfully submits that claim 12 is allowable for at least the reason that it recites features that are neither disclosed, taught nor suggested by either of the proposed combinations. Further, Applicant respectfully submits that dependent claim 13-17,

which depend from allowable independent claim 12, are allowable for at least the reason that they depend from an allowable independent claim. *In re Fine,* 837 F.2d 1071, 5 USPQ 2d 1596, 1598 (Fed. Cir. 1998).

CONCLUSION

For at least the foregoing reasons, Applicant respectfully requests that all outstanding rejections be withdrawn and that all pending claims of this application be allowed to issue. If the Examiner has any comments regarding Applicant's response or intends to dispose of this matter in a manner other than a notice of allowance, Applicant requests that the Examiner telephone Applicant's undersigned attorney.

Respectfully submitted,

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